00270

TUL2AUSA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	) Group Art Unit: 1645
M. Philipp	) Examiner: R. Swartz
Appln. No. 09/445,803	)
Filed: December 13, 1999	)
For: SURFACE ANTIGENS AND PROTEINS USEFUL IN COMPOSITIONS FOR THE DIAGNOSIS AND PREVENTION OF LYME DISEASE	)

Box AF
Commissioner for Patents
Washington, DC 20231

DECLARATION PURSUANT TO 37 CFR § 1.131

Sir:

I, Mario T. Philipp, Ph.D., residing at 248 Shaunell Drive, Mandeville, Louisiana, USA, a citizen of the Republic of Germany, do declare and state that:

1. I am the named inventor of the above-identified patent application.

2. This Declaration is submitted to establish conception and reduction to practice of the invention in this application by work conducted either in the United States, a NAFTA country after December 8, 1993, or a WTO member country after January 1, 1996. Specifically, this Declaration establishes conception and reduction to practice of the invention in this application in the United States at a date prior to the effective date of April 18, 1997, coupled with due diligence in reduction to practice in the United States from prior to said effective date to subsequent reduction to practice. All experiments and work described herein were performed in the United States. The

E

evidence in the attached documents supports conception prior to April 18, 1997 through to a reduction to practice. The reduction to practice is supported by the filing of the earliest US Provisional Patent Application No. 60/051,271 on June 30, 1997 for which priority is claimed.

3. The effective date of April 19, 1997 identified in the previous paragraph is the publication date of the Zhang et al. document, i.e., "*Antigenic Variation in Lyme Disease Borreliae by Promiscuous Recombination of VMP-like Sequence Cassettes*", Cell, 89:275-285 (April 18, 1997) (hereinafter "Zhang"). Zhang was cited by the Examiner in the Office Action dated September 18, 2002 in this application as a basis under 35 USC § 102(b) for a novelty rejection of pending claims 10-13, 39, 67, 81, 83, 100, and 102.

4. To establish conception of the invention of this application, pages of a Report and Grant Application labeled Exhibits A and B are provided and submitted as evidence. These documents were prepared by me or under my supervision. The experiments described therein were performed by me or under my instruction in the United States. These documents discuss the results of experiments performed in the United States prior to the effective date. All dates on the pages of the Report and Department of Health and Human Services Grant Application have been masked. Exhibits A and B are in chronological order from earlier date to later date.

5. Exhibit A includes the coversheet and pages 52 and 53 from a Department of Health and Human Services Grant Application prepared by myself and labeled "Grant Application". This document describes the cloning of P39.5 and eleven cloned fragments produced therefrom. One specific clone, i.e., the 7-1 clone, was selected for overexpression and purification. I sequenced the 7-1 clone as reported in the priority US Provisional Patent Application No. 60/051,271. The identity of the 7-1 clone was confirmed and found to be about 950-bp in length. The sequence of the 7-1 clone was obtained using procedures known by those of skill in the art.

E

The "Grant Application" further describes that an 1190 bp partial sequence was obtained. Of this 1190 bp sequence, 950 bp was derived from the 7-1 clone and 150 bp, which is located 5' to the 7-1 segment, was derived from clone 14. This 1190 bp sequence is the total sequence of SEQ ID NO:1 of the priority US Provisional Patent Application No. 60/051,271 and the total sequence of SEQ ID NOS: 1 and 13 of the present application.

6. Exhibit B includes the coversheet and page 7 from the "Report of the Identification of a New Antigen of *Borrelia garinii* that is a Vaccine Candidate" prepared by myself and labeled "Vaccine Candidate Report". The information provided on page 7 provides the same information noted in the "Grant Application" described in section 5 and specifically the isolation and sequencing of the 7-1 clone.

7. I, the inventor, worked continuously from the date that I conceived the invention and performed the acts described in Paragraphs 4-6 to at least the time of the filing of US Provisional Patent Application No. 60/051,271 on June 30, 1997 by performing additional experiments on this invention and assisting in the drafting of this patent document. The filing of the application establishes diligence to reduction to practice of the invention.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date 3-12-03

By _____
Mario T. Philipp, Ph.D.

E